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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,218	04/15/2004	Paolo C. Trubiano	3085.ENC	1170

7590

09/16/2005

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EXAMINER

BRADRICK, THOMAS DALE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,218

Applicant(s)

TRUBIANO ET AL.

Examiner

Thomas D. Bradrick

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/15/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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Art Unit: 1651

DETAILED ACTION

Claims 1-21 are pending. Claims 1-17 are considered on the merits.

Claims 18-21 are withdrawn from consideration as being drawn to a non-elected invention. Election was made **without** traverse in the reply filed on 15 July 2005.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman *et al.* [A] or von Lengerich [B] in view of Blue *et al.* [C].

Claims 1-17 are drawn to a) a composition comprising an active agent encapsulated in a mixture comprising at least one modified starch and at least one protein (claim 1). The modified starch is further specified as b) being derivatized by octenylsuccinic anhydride (claims 2 and 4) and c) degraded by glucoamylase, for example (claims 3 and 4), while the protein is further specified to be either d) a casein (*e.g.*, sodium caseinate) or e) soy protein (claims 5-8). The active agent is further specified to be f) oxygen sensitive or g) an oily substance such as omega-3 fatty acid (claims 9-11). Various characteristics of the starch and mixture, such as h) the dextrose equivalence (claim 12), i) viscosity (claim 13), j) starch-to-protein ratio (claims 14 and 15), and k) amount of active agent encapsulated (claims 16 and 17) are also specified.

Crossman *et al.* [A] disclose the use of modified starches (*e.g.*, octenyl succinic anhydride modified- and glucoamylase treated- (Example 4)) as encapsulating agents in carriers of oil well chemicals. Crossman *et al.* [A] also provide for the inclusion of other ingredients typically used to improve control of the encapsulated active agent's release, such as gelatin, gum Arabic and (a and e) soy protein [col. 5, l. 5 ff]. von Lengerich [B] also provides for the use of casein as well as soy protein [col. 8, l. 24 ff] in controlling the release of an encapsulant from a matrix that may comprise modified starches. Crossman *et al.* [A] or von Lengerich [B] do not provide for the specifics of the modified starch in terms of dextrose equivalence and viscosity, the starch-to-protein ratio and the amount of active agent encapsulated. Crossman *et al.* [A] and von Lengerich [B] do show,

Art Unit: 1651

as indicated above, that the addition of release control ingredients to modified starch encapsulators is known in the art.

Blue *et al.* [C] disclose the use of c) glucoamylase-converted starch derivatives as encapsulating agents. After using b) octenylsuccinic anhydride [col. 4, l. 9 and Example 1] to prepare a starch derivative containing a hydrophobic group or both a hydrophobic and a hydrophilic group [Abstract], the derivatized starches are further modified by c) enzymatic hydrolysis using glucoamylase [Example 2]. The resulting starch is claimed to have i) a viscosity of less than 30 seconds [col. 5, l. 50] and h) a dextrose equivalent of at least 20 and up to about 80 [col. 6, l. 16]. The resulting modified starches are revealed to possess high load and retention of the active ingredient, low surface oil exposure and excellent oxidation resistance [Abstract] and may be used to encapsulate g) oils, fats, flavors, colors, fragrances, and pharmaceuticals and, in particular, flavor oils and vitamins [col. 6, l. 28 ff]. The encapsulating agents are also claimed to provide a relatively high level of oxidation resistance [col. 7, l. 22], based on the less than 0.8% conversion of limonene in f) citrus oil to carvone. Load levels of k) greater than 60% by weight of the encapsulating agent, are claimed [col. 6, l. 54].

In light of the above, it would have been obvious to one of ordinary skill in the art to substitute a modified starch of the required specifications and characteristics (as taught by the secondary reference of Blue *et al.* [C]) in the compositions of the primary references (Crossman *et al.* [A] and von Lengerich [B]) in order to obtain the composition of the claimed invention, with the

Art Unit: 1651

reasonable expectation that this would constitute the substitution of an acceptable equivalent. The optimal amount of casein or soy protein to be used could be determined by a reasonable amount of experimentation, and it would be reasonable to use the starch and protein mixture to encapsulate any material that would be compatible with the encapsulants, including oils and vitamins as revealed by the secondary reference (Blue *et al.* [C]). The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, claims 1-17 are properly rejected under 35 U.S.C. § 103.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is (571) 272-8139. The examiner can normally be reached Monday through Friday between 8:30 a.m. and 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Bradrick
Patent Examiner
Art Unit 1651



SANDRA E. SAUCIER
PRIMARY EXAMINER